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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/023,711

12/21/2001

Akira Imaizumi

US-1460

6895

38108 7590 11/09/2007

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

11/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/023,711	<b>Applicant(s)</b> IMAIZUMI ET AL.	
	<b>Examiner</b> Christian L. Fronda	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 April 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 6-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 7-10 and 12-14 is/are rejected.
- 7) ☒ Claim(s) 6 and 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

1. The finality of the previous Office Action has been withdrawn. The amendment filed 04/26/2007 has been entered.
2. Claims 1 and 6-14 are pending and under consideration in this Office Action.

#### *Claim Rejections - 35 U.S.C. § 112, 1st Paragraph*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 7-10, 12-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for a method for producing L-lysine, L-glutamic acid, and L-tryptophan using an *Escherichia coli* bacterium whose endogenous RMF protein is mutated so that the RMF protein is inactive, wherein said L-lysine, L-glutamic acid, and L-tryptophan are produced in larger quantities than if said RMF protein is active; does not reasonably provide enablement for any other embodiment as recited in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicants' arguments filed 04/26/2007 have been fully considered but are not persuasive.

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The examiner respectfully disagrees with applicants' position for reasons of record as further explained that one of ordinary skill in the art would be able to predict that production of L-amino acids other than L-lysine, L-glutamic acid, and L-tryptophan in an *Escherichia coli* bacterium where the endogenous *Escherichia coli* gene encoding the RMF protein is mutated so that the RMF protein is inactive.

As previously stated, the nature and breadth of the claims encompass any method for the production of any L-amino acid using an *Escherichia coli* bacterium whose endogenous RMF protein is mutated so that the RMF protein is inactive. The specification provides guidance and working examples for an *Escherichia coli* bacterium having its endogenous RMF protein inactivated which over produces L-lysine (Example 2 of the instant specification), L-glutamic acid (shown in the declaration of Akira Imaizumi filed 03/28/2005), and L-tryptophan (shown in the declaration of Akira Imaizumi filed 05/05/2006).

However, the specification and the Declarations under C.F.R. §1.132 submitted 03/28/2005 and 05/10/2006 do not provide guidance, prediction, and working examples for any other L-amino acid that can be produced by an *Escherichia coli* bacterium having its endogenous RMF protein inactivated. It is not clear how overproduction of L-lysine, L-glutamic acid, and L-tryptophan would lead to one of ordinary skill to predict overproduction of any other L-amino acid. The reference of Imaizumi et al. (Biosci Biotechnol Biochem. 2006 Apr;70(4):949-57) teaches that while disruption of the *rmf* gene increased the L-lysine productivity of the WC196 lysine-overproducing strain of *Escherichia coli* K-12, it is still unclear what happens in the *rmf* disruptant (see entire publication, especially page 949, left column, last paragraph). Imaizumi et al does not demonstrate elevated expression of any particular genes involved in amino acid biosynthesis in the *rmf* disrupted *E. coli*. Imaizumi et al teaches significant down regulation of ribosomal protein coding genes and related genes in a *rmf* disrupted *E. coli* (see page 955, right column, last paragraph to page 956). Furthermore, the reference of Chou et al. (Biotechnol

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Bioeng. 1996; 50: 636-642; PTO 1449 for the IDS dated 06/30/2003) teaches no enhancement of protein production using *lac* promoter system in a *rmf* disrupted *E. coli*.

Therefore, in view of the unpredictability in the art an undue amount of trial and error experimentation must be preformed where such experimentation involves inactivating the endogenous RMF protein in any *E.coli* bacterium, culturing the bacterium in any medium, and searching and screening for any L-amino acid that can be over produced. General teaching regarding screening and searching for the claimed invention is not guidance for making the claimed invention. Thus, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)).

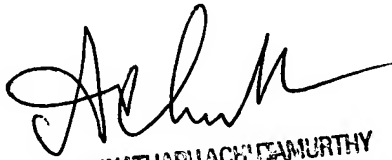
### ***Conclusion***

5. No claim is allowed.
6. Claim 6 and 11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Thursday and alternate Fridays between 9:00AM - 6:30PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000. CLF



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